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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,470

Applicant(s)

FRASER ET AL.

Examiner

Padmavathi v. Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-81 is/are pending in the application.
- 4a) Of the above claim(s) 3-21 and 24-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3-21 and 24-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/9/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response

1. Applicant's response to restriction filed on 6/10/05 is acknowledged.

Election

2. Applicant's election of Group 1 claims 1 and 2 and SEQ ID NO: 1 in the reply filed on 6/10/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

3. No New claims have been added.

No claims have been amended

Claims 1-21, 24 and 25-81 are pending in the application.

Claims 1-2 are elected and are under examination.

Claims 3-21, 24 and 25-81 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/10/05.

Priority

4. This application 10/018470 is a national stage entry of PCT/US00/05928 International Filing Date: 03/08/2000 Which Claims Priority from Provisional Application 60/132,068, 4/30/1999.

Information Disclosure Statement

5. The Information Disclosure Statement filed on 9/9/2002 is reviewed and a signed copy of each is enclosed to this Office action.

Sequence Rule Non-compliance

6. It is noted that on pages 58 and 59 contain nucleic acid sequences (more than 10 nucleic acids). However, they are not identified by sequence identification numbers. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R. 1.821 through 1.825. All SEQ ID numbers recited in the specification and/or the claims must be included in the Sequence Listing. Note that branched sequences are specifically excluded from this definition.

7. Applicants must submit such a paper copy or CD ROM and an amendment directing its entry at the appropriate section of the specification via an amendment.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821 -1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. 1.821(g). Applicant is advised to review the entire specification once again for any other sequences that have not been identified and that there is no new matter has been introduced into the Specification.

Specification – informalities

8. The specification of the instant application is objected to for the following reasons:

- (a) To be consistent with the labeling used in the drawings, under "Brief Description of the Figures " Applicants should refer to 'Figure 1- Figure 9 for example: as –Figure 1A- 1D- Figure 9 A-Figure 9D etc.

It is noted that the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors.

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For example:

- (a) Pages 58-59 recite sequences that are not identified by the sequence identification numbers. Therefore, applicant is advised to insert the sequences identification numbers.
- (b) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code see in particular at least pages 5 and 8 refer to worldwide web address. The worldwide web address can be readily changed with rapidly changing technology and therefore, may not be available to the public. Therefore, applicant is advised to amend the specification and use some other means to recite the sequence. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

10. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The method as claimed is a mathematical algorithm without any concrete or tangible steps (i.e., no physical steps).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the abbreviation "NMB" is used without definition upon their first appearance in the claim.

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Claim 1 is vague for the recitation of "NMB open reading frames." In the absence of any structural properties it is difficult to understand what corresponds to said NMB open reading frames.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it fails to recite any process step that relates to the purpose set forth in the preamble. It is unclear whether preamble or the actual step controls the metes and bounds of the claim.

Claim Rejections - 35 USC 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribot et al 1998, WO - A 9817805 (see IDS 9/9/02).

Claims are drawn to a method for identifying an amino acid sequence, comprising the step of searching for putative open reading frames or protein-coding sequences within one or more of *N meningitidis* nucleotide sequences selected from the group consisting of SEQ ID NO 1 and the NMB open reading frames, said method further comprises steps of searching a *N. meningitidis* nucleotide sequence for an initiation codon and searching the upstream sequence for an in-frame termination codon.

Ribot et al disclose an automated DNA sequence analysis of PCR fragments using dye terminator reaction method (see page 57, lines 2-7) for identifying serogroup B amino acid

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sequences comprising the step of computer assisted analysis (i.e., searching see page 57, lines 5-7) for putative open reading frames (see Figure 1, SEQ.ID.NO: 6 and SEQ.ID.NO: 3) or coding an amino acid sequence within *N meningitidis* nucleotide sequence (prior art SEQ.ID.NO: 1). As shown in prior art SEQ ID NO: 1 the sequence comprises initiation codon (i.e., ATG see SEQ.ID.NO: 1, line 1, position 16-18) and an in-frame termination codon (see SEQ.ID.NO: 1 of prior art, position 1100 and 1148). The prior art discloses a method for searching ORFS or protein coding sequence of *Neisseria meningitidis*. Therefore, the claimed ORFS of SEQ.ID.NO: 1 are within the gene coding for NMB of the prior art. Thus the prior art anticipated the claimed invention.

15. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Brodeur et al 1996, WO – A 9629412.

Claims are discussed supra

Brodeur et al disclose a method of (pNP2202 clone carrying 2.75kb insert) sequencing the gene coding for *Neisseria meningitidis* serogroup B surface protein (22kD see page 16 figure 1) using Taq Dye Deoxy Terminator Cycle Sequencing method (see page 41). This method comprises the step of searching (see page 42, lines 20-30) and analyzing the insert, that was sequenced in both directions for putative open reading frames (see prior art SEQ.ID.NO: 1 or coding an amino acid sequence) within *N meningitidis* nucleotide sequence. As shown in prior art SEQ ID NO: 1 the sequence comprises initiation codon (i.e., ATG, see SEQ.ID.NO: 1, of prior art) and an in-frame termination codon (see TGA 1). Thus the prior art discloses a method for searching ORF or protein coding sequence of *Neisseria meningitidis*. Therefore, the claimed method for searching ORF of SEQ.ID.NO: 1 is within the method for searching a gene coding for NMB of the prior art. Thus the prior art anticipated the claimed invention.

Relevant Prior Art

16. The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

Pietrokovski Shmuel (Tutorial notes, 1999, (Molecular Genetics, The Weizmann Institute of Science, Rehovot Israel) teach proteins can be grouped together in families where all members have the same, or similar, function and are descended from a common ancestor. Proteins from the same family are usually composed of highly conserved sequence regions separated by regions of different lengths and little sequence similarity. These conserved sequence regions, called motifs, are typically 6-30 aa long and correspond to active sites, substrate or ligand binding sites, and structurally important segments of proteins. Motifs can be identified by multiple-sequence alignments of proteins. Multiple alignments of motifs, called blocks, are extremely useful in various areas of protein research. In particular they are effective in identifying new family members through database sequence searches, in predicting the proteins function and structure, and in designing PCR primers to amplify genes of unknown family members.

Oliff et al EP-A467714, 1992 (see IDS 9/9/02) disclose recombinant cloning and expression of DNA encoding the immunoenhancing protein using expression vector.

Snyder et al teach (*Microbiology* 2001, 147, 2321-2332) a complete genome analysis of *Neisseria meningitidis* strain MC58, the largest repertoire of putative phase-variable genes described in any species. Initial comparisons with two incomplete *Neisseria* spp. genome sequences available at that time revealed differences in the repeats associated with these genes in the form of polymorphisms, the absence of the potentially unstable elements in some alleles, and in the repertoire of the genes that were present. Analyses of the complete genomes of *N. meningitidis* strain Z2491 and *Neisseria gonorrhoeae* strain FA1090 have been performed and are combined with a comprehensive comparative analysis between the three available complete genome sequences. This has increased the sensitivity of these searches and provided additional contextual information that facilitates the interpretation of the functional consequences of repeat instability.

Pellicic et al teach (*JOURNAL OF BACTERIOLOGY*, Oct. 2000, p. 5391-5398) an in vitro *Himar1* mariner transposition on chromosomal or PCR amplified meningococcal DNA, which is subsequently reintroduced into *N. meningitidis* by natural transformation,

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is an extremely efficient mutagenesis method. Southern blot analysis, sequencing the *Himar1* insertion point in numerous transposition mutants, and a limited screening of the mutant libraries for clones impaired in maltose catabolism confirmed that *Himar1* transposed randomly in *N. meningitidis*. Taken together, these data demonstrate that *Himar1* in vitro transposition can lead to the exhaustive mutagenesis of *N. meningitidis*, allowing for the first time a genomic-scale mutational analysis of this important human pathogen.

T.Rognes July 2000, Institute of Medical Microbiology, Ph.D thesis, pages 1-35, teach rapid and sensitive methods for protein sequence comparison and database searching.

Remarks

17. No claims are allowed.

Conclusion

18. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A

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message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.


NTA MINNIFIELD
PRIMARY EXAMINER
8/22/05